

REMARKS

I. Status of the Claims

Claims 1-15 are presently pending. Applicant requests reconsideration of the present application in view the Declaration of Thierry Burnouf ("Burnouf Declaration") submitted herewith and the reasons that follow.

II. Rejections Under 35 U.S.C. § 112

The examiner rejects claims 1-15 under 35 U.S.C. § 112, ¶1, for allegedly containing "new matter". Applicant traverses the rejection.

According to the examiner, the specification does not support claim 1's recitation of a "linear flow rate of at least 1,500 cm/hour". This assertion is factually incorrect, however. One of skill in the art reviewing the specification would recognize instantly that the phrase "1.500 cm/hour" contains a punctuation error and that the decimal point (".") should be read as a comma (","), *i.e.* "or 1,500 cm/hour" or "1500 cm/hour". *See* Burnouf Declaration, ¶ 5-9. In one aspect, a skilled person would recognize instantly that reciting a flow rate to 3 significant figures (*i.e.* at an accuracy rate of 10 µm or "1½ cm/hour") is unrealistic in this context. *Id.* at ¶ 8.

Furthermore, the specification makes it perfectly clear that the term "1.500 cm/hour" refers to "1500 cm/hour" or 25 cm/min. *Id.* at ¶ 5. For example, the specification notes that "[o]ne major advantage of the invention relates to the utility of high flow rates, rather than the conventional ones which amount to about 200 cm/hour." *See* US 2007/0092960, ¶ [0061]; Burnouf Declaration, ¶ 5. Thus, the specification makes it clear that the inventive methods employ **high flow rates**, rates which must be at least *above 200 cm/hour*. Burnouf Declaration, ¶ 5.

In addition, the specification states that "[p]referably, the linear flow rate may be operated within the range from 1.800 to 10.000 cm/hour, such as within the range of 2.000 to 10.000 cm/hour, such as typically at linear flow rates of about 3000 to 7000 cm/hour." US 2007/0092960, ¶ [0061]; Burnouf Declaration, ¶ 6. As the range "3000 to 7000 cm/hour" cannot lie between a range of 1.8 and 10 cm/hour, one of skill in the art reviewing the text would recognize immediately that the recited decimal point (".") must be read as a comma, as one often does with Danish language texts. Burnouf Declaration, ¶ 6. Likewise, a skilled person reviewing original claim 13 would understand that the recited "1.500 to 12.000 cm/hour" must be read as "1,500 to 12,000 c/m hour" so as to encompass the recited "3000 cm/hour". *Id.*

Further support can be found in the examples. *Id.* at ¶ 7. Example 1 discloses the isolation of lactoferrin using a column with diameter of 30 cm. US 2007/0092960 at [0120]; Burnouf Declaration, ¶ 7. The example shows that a total volume of 3459 l was processed in 3.26 hours. Burnouf Declaration, ¶ 7. As this flow rate equates to 1,500 cm/hour, a skilled person reviewing the specification would recognize that the example's recitation of "1.500 cm/hour" actually denotes "1,500 cm/hour". *Id.* Meanwhile, Examples 2, 3, 4 and 12 specifically evaluate a flow rate of "1,500 cm/hr", among others. *Id.*

Moreover, a practitioner would appreciate that a linear flow rate of just 1½ cm/hour (*i.e.* 2½ mm/minute) is inoperable in the field of expanded bed technology. *Id.* at ¶ 8. Stated simply, a chromatographic bed can not "expand" at such extremely slow flow rates. *Id.*

Accordingly, a person of skill in the art reviewing the specification would recognize readily that applicant possessed at the time of filing an isolation process employing a "linear flow rate of at least 1,500 cm/hour", as presently claimed. *Id.* at ¶ 4-9. Thus, the requirements of §112, ¶1 have been satisfied. Applicant requests, therefore, that the rejection be withdrawn.

III. Objections to the Specification

The examiner objects to the amendments entered in the last response to correct punctuation errors in the specification as allegedly constituting "new matter". Applicant traverses the objection. In particular, for all the reasons noted above, one skilled in the art would not only recognize the existence of the noted errors in the specification, but also the appropriate correction. *See, e.g.* Burnouf Declaration, ¶ 9. Thus, the entered amendments do not constitute "new matter". *See* MPEP §2163.07 (Pg. 2100-191; Rev. 6, Sept. 2007). Applicant requests, therefore, that the objection be withdrawn.

IV. Rejections Under 35 U.S.C. § 103

The examiner rejects claims 1-15 over Kawakami *et al.* as evidenced by Hirai *et al.*, Mitoma *et al.*, Yoshida *et al.* and Ahern. Applicant traverses the rejection.

Kawakami is invoked for its alleged teaching of a process for isolating lactoferrin using a chromatographic column with a flow rate of 3.1 cm/min (*i.e.*, 186 cm/hr) and a process temperature of 50°C. While the examiner admits that Kawakami fails to teach a process employing a flow rate of at least 1500 cm/hr, he nonetheless asserts that an artisan would have been motivated to adapt

Kawakami's process to an "industrial scale" because Ahern states that "faster flow rates lead to quicker separations with better resolution" and that "liquid chromatography performed under pressure is a powerful analytical and preparative tool for chemists and life scientists." Office Action, pg. 9. Such generalized statements, however, cannot support a *prima facie* case of obviousness.

As an initial matter, applicant notes that no combination of the cited material yields an isolation process employing high temperature (at least 40°C) and high flow rate (at least 1,500 cm/hour) as presently claimed. For this reason alone, the examiner has failed to establish a *prima facie* case of obviousness.

The examiner also has failed, however, to establish a motivation for combining the cited references. In this regard, the examiner's reliance upon Ahern's recitation of advantages of faster flow rates for packed bed columns is misplaced. As conditions applicable to packed bed chromatography are not comparable to those for expanded bed chromatography, Ahern's comment would not have led an artisan to modify Kawakami's method to reach the claimed processes.

Applicant submits that the application is in condition for allowance. Examiner Kim is invited to contact the undersigned directly, should he feel that any issue warrants further consideration.

The Commissioner is hereby authorized to charge any additional fees, which may be required under 37 C.F.R. §§ 1.16-1.17, and to credit any overpayment to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account. If any extension is needed for timely acceptance of submitted papers, then applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of the relevant fee from the deposit account.

Respectfully submitted,

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